The opinion in support of the decision being entered today was <u>not</u> written for publication in a law journal and is <u>not</u> binding precedent of the Board.

Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEPHEN C. WARDLAW

Appeal No. 2003-1489
Application No. 09/256,486

ON BRIEF

Before KIMLIN, GARRIS and KRATZ, <u>Administrative Patent Judges</u>.

KIMLIN, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1-15, 17-20, 22, 23, 28, 29, 31, 33 and 40-44. Claims 21 and 24-27, the other claims remaining in the present application, have been allowed by the examiner. Claim 1 is illustrative:

1. A container for holding a biologic fluid sample for analysis, said container comprising:

a chamber having a first wall and a transparent second wall, wherein a fluid sample quiescently residing within said chamber is imageable through said second wall;

at least one feature operable to enable the analysis of the biologic fluid, said feature located within said chamber at a known spatial location; and

a label attached to said container, said label containing information having utility in said analysis, said information including said known spatial location.

The examiner relies upon the following references as evidence of obviousness:

Van Deusen et al.	5,132,097	Jul.	21,	1992
(Van Deusen) Gavin et al.	5,591,403	Tan	0.7	1997
(Gavin)	3,391,403	van.	0 / ,	1991
O'Bryan et al. (O'Bryan)	5,623,415	Apr.	22,	1997

Appellant's claimed invention is directed to a container for holding a biologic fluid sample for the purpose of analyzing the sample. The container comprises a chamber in which a fluid sample quiescently resides and is imageable through a transparent wall. The container also comprises at least one feature, which is located within the chamber at a known spatial location, that enables analysis of the biologic fluid. The feature may be a reagent which reacts with the fluid sample in the chamber (claim 15), and may further include a through-plane thickness located at or adjacent the known spatial location (claim 17). In addition, the container comprises a label containing information that is useful regarding the analysis, including the spatial location of the feature.

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Appealed claims 1-6, 8-15, 17-20, 22, 23, 28, 29, 31, 33 and 40-44 stand rejected under 35 U.S.C. § 103 as being unpatentable over Gavin in view of Van Deusen. Claim 7 also stands rejected under 35 U.S.C. § 103 as being unpatentable over Gavin in view of Van Deusen and O'Bryan.

In accordance with the grouping of claims set forth at page 8 of appellant's principal brief, the following groups of claims stand or fall together:

- (A) claims 1-10, 12-15, 22, 23, 28 and 29;
- (B) claim 11;
- (C) claim 31;
- (D) claim 33; and
- (E) claims 17-20 and 40-44.

We have thoroughly reviewed each of appellant's arguments for patentability. However, we are in complete agreement with the examiner that the claimed subject matter would have been obvious to one of ordinary skill in the art within the meaning of § 103 in view of the applied prior art. Accordingly, we will sustain the examiner's rejections for essentially those reasons expressed in the Answer, and we add the following primarily for emphasis.

We concur with the examiner that Gavin, like appellant, discloses a container for holding a biologic fluid sample for analysis comprising a chamber having a transparent wall which contains the sample that is imageable through the transparent wall. The container of Gavin also comprises the claimed "at least one feature operable to enable the analysis of the biologic fluid" (claim 1), such as a reagent disposed in the chamber which reacts with the sample, and a through-plane thickness located at the known spatial location that is substantially less than the lateral expanse of that region of the chamber. In addition, the container of Gavin comprises a label, or bar code, which contains useful information for the analysis. While the information on Gavin's label is not described as including the spatial location of the reagent, Van Deusen evidences that it was known in the art to include the spatial location of a reagent on the label of a testing device. Accordingly, we find no error in the examiner's legal conclusion that it would have been obvious for one of ordinary skill in the art to provide such information with a label on a testing device of the type disclosed by Gavin. Manifestly, it would be a matter of obviousness for one of ordinary skill in the art to include all the information on such

a label that is physically practical and useful for the intended test.

While appellant acknowledges that "[t]he Examiner correctly observes that there is no recitation of a means to image the container within the claim," appellant nonetheless argues that no imaging is performed by Gavin, "[n]or is it disclosed or suggested that the container within Gavin includes a chamber having a wall through which a fluid quiescently residing within the chamber is imageable." We agree with the examiner, however, that the transparency of Gavin's container renders it "fully capable of performing the imaging function." Appellant, in response, offers only the conclusion that the examiner's finding "is unfounded and appears to be the product of impermissible hindsight," but appellant advances no substantive argument which provides a rationale why the fluid sample in the transparent container of Gavin is not capable of imaging. Appellant only repeats what is acknowledged by the examiner, namely, that

¹ Page 12 of principal brief, second paragraph.

² Sentence bridging pages 11 and 12 of principal brief.

³ Page 8 of Answer, first paragraph.

⁴ Page 12 of principal brief, first paragraph.

"[t]here is no disclosure or suggestion that imaging is performed within <u>Gavin</u> regardless of the type of light source."⁵

Appellant also maintains that there is no disclosure in Gavin regarding the known spatial location of the "feature" (clot-promoting agent 28). However, appellant acknowledges that Gavin discloses that agent 28 is located between the restricted areas 42 and the drive apertures 35 of the conduits, and such disclosure meets the claimed requirement of a feature located within the chamber at a known spatial location. Also, inasmuch as appellant's specification defines "feature" as including physical and geometric characteristics of the chamber, Gavin's disclosure of restricted area 42 meets the claimed requirement for such feature.

We are also not persuaded by appellant's argument that "[n]either <u>Gavin</u> nor <u>Van Deusen</u> disclose [sic, discloses] or suggest [sic, suggests] a container having a chamber for quiescently holding a biologic sample, wherein the sample can be imaged within the chamber." Again, appellant has not refuted the examiner's reasonable finding that the chambers of Gavin are fully capable of quiescently holding a sample which can be

⁵ Page 12 of principal brief, last sentence.

⁶ Page 14 of principal brief, first paragraph.

imaged. Whereas appellant goes to great lengths to emphasize that the "wherein" clause of the claim "describes a characteristic of the second wall," appellant does not explain why the transparent wall of Gavin's chamber does not possess this characteristic.

Regarding the separately argued requirement of claim 11 for the label containing information for accessing information stored remotely from the label, we find, as set forth above, that it would have been obvious for one of ordinary skill in the art to include all information on the label that is useful in the process in which the container is used. Certainly, one cannot patentably distinguish an article from a prior art article by labeling it with instructions for using the article in a manner not disclosed by the prior art.

Separately argued claim 31 calls for "at least one feature includes physical characteristics located at known spatial locations within a plurality of regions of said chamber, and said physical characteristics enable the performance of a plurality of different tests on the biologic fluid sample." We agree with the examiner that this requirement is met by "Figures 2 and 5 of Gavin et al. for the teaching of different regions on either side

⁷ Page 14 of principal brief, last sentence.

of the restriction 42, in the chambers 30-34, which can contain different reagents 28, 29, 39."8 As explained by the examiner, "Gavin et al. shows a chamber that includes a plurality of regions, each region having through-plane thickness that enables the performance of a plurality of different tests on the biological sample." The examiner's analysis rebuts appellant's argument that "[t]here is no disclosure of any physical characteristics within any of the conduits 30-34 that enable the performance of a plurality of different tests."10 As for separately argued claim 33, appellant has advanced no reason why the structure of Gavin's container does not allow for the claimed iterative performance of a test. The fact that Gavin discloses, as urged by appellant, that the cuvette 12 can be disposed once a PT test has been completed does not mean that iterative tests cannot be performed before disposal. Indeed, as noted by the examiner, appellant's specification teaches that a distinct advantage of the claimed container is that it is disposable.

Concerning the recitation in claims 17 and 40 pertaining to the relative size of the through-plane thickness versus the

⁸ Page 12 of Answer, second paragraph.

⁹ Id.

¹⁰ Page 20 of principal brief, third paragraph.

lateral expanse of a first region of the chamber, we agree with the examiner's reasoning set forth at pages 14 and 15 of the Answer. Although appellant submits that "[i]nherency does not obviate the Examiner's burden of providing a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art," appellant has failed to address just such reasoning provided by the examiner. Nor has appellant provided any reasoning or evidence which demonstrates that the chambers of Gavin do not meet the claimed relationship between through-plane thickness and lateral expanse.

As a final point, we note that appellant bases no argument upon objective evidence of nonobviousness, such as unexpected results.

In conclusion, based on the foregoing and the reasons well-stated by the examiner, the examiner's decision rejecting the appealed claims is affirmed.

¹¹ Sentence bridging pages 23 and 24 of principal brief.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR \$ 1.136(a).

<u>AFFIRMED</u>

EDWARD C. KIMLIN Administrative Patent	Judge)	
BRADLEY R. GARRIS Administrative Patent))) Judge)))	BOARD OF PATENT APPEALS AND INTERFERENCES
PETER F. KRATZ	,) , Judge)	

ECK:clm

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